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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,875	03/23/2005	Janet A. Halliday	4017-003	8764

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
08/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,875	HALLIDAY ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 6-22* is/are pending in the application.

4a) Of the above claim(s) *7 and 14-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 6, 8-13 and 21-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 05/26/09 are acknowledged.

2. Claims 4-5 were cancelled. Claims 7 and 14-20 were withdrawn from consideration. New claims 21-22 were added. Claims 1, 6 and 7 were amended.

3. Claims 1-3, 6, 8-13 and 21-22 are included in the prosecution.

Response to Arguments

Rejections under 35 USC § 102(b)

4. Applicants' arguments, see Page 5, filed 05/26/09, with respect to the anticipation rejections of claims 1-3 over Fildes et al. (US 4,202,880), of claims 1-4 over Yu et al. (Biomaterials), and of claims 1-4 and 13 over Graham et al. (WO 94/22934) have been fully considered and are persuasive in light of the amendment of claim 1 (to recite a C_5 to C_{20} diol). Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Hoy et al. (US 4,426,485).

Rejections under 35 USC § 103(a)

5. Applicants' arguments, see Page 5, filed 05/26/09, with respect to the rejection of claims 1-6 and 8-12 under 35 USC § 103(a) as being unpatentable over Fildes et al. (US 4,202,880) in view of Wunder et al. (US 3,639,157) have been fully considered but are not persuasive.

Applicants argue that Wunder does not disclose or suggest a polyurethane (or any other polymer) made from polyethylene glycol, 1,10-decane diol, and 4,4' –

dicyclohexyl methane diisocyanate. Applicants argue that in contrast to the Office assertions, Wunder's polyol is either a polyhydric polyalkylene ether (e.g., polyethylene glycol-1000 and the like) or a polyhydric polyester (the product of a dicarboxylic acid and a polyhydric alcohol such as 1,10-decane diol), but not both. Applicants argue that there is nothing in Wunder to support the Office's basis for combining the references, and the rejection cannot be sustained on such grounds.

This is not persuasive because the primary reference, Fildes, teaches the preparation of a linear copolymer of polyethylene glycol, a diisocyanate and one or more dihydroxy compounds. One of ordinary skill in the art would find it obvious to use different molecular weight polyethylene glycols, different diisocyanates and different dihydroxy compounds (diols) and test the combinations for the desired swelling in water during the process of routine experimentation. The use of polyethylene glycol, 1,10-decane diol and 4,4'-dicyclohexyl methane diisocyanate in polyurethanes is disclosed by Wunder. Wunder specifically teaches that polyethylene glycol, 1,10-decane diol and 4,4'-dicyclohexyl methane diisocyanate are suitable components of a polyurethane. One of ordinary skill in the art would use these components in the composition of Fildes with a reasonable expectation of success in producing a functional polymer. Exemplary rationales that may support a conclusion of obviousness include: Combining prior art elements according to known methods to yield predictable results. Please see MPEP 2141.

Applicants argue that: "one would not expect Wunder's polyurethane co-polyalkylene ether or polyurethane co-polyester to have the same hydrophilic or

amphipathic properties as Fildes' ABABAB linear block copolymer. One would not expect Wunder's polyurethane co-polyalkylene ether or polyurethane co-polyester to have the same hydrophobicity as Fildes' polyurethane B region. Indeed, one would not expect Wunder's polyurethane co-polyalkylene ether to have the same hydrophilic/hydrophobic properties as Wunder's polyurethane co-polyester. Thus, expectation of success is lacking, and the rejection cannot be sustained on such grounds".

This is not persuasive because the general teaching of Fildes would lead one of ordinary skill in the art to try various components to prepare a copolymer of polyethylene glycol, a diisocyanate and a dihydroxy compound. It would have been obvious to one of ordinary skill in the art at the time the invention was made to choose from a finite number of predictable diisocyanates and dihydroxy compounds (diols) in the linear polymer composition with a reasonable expectation of success of producing a functional linear polymer.

Regarding the combination of references, all the claimed elements are found in Fildes and Wunder and one with ordinary skill in the art could have combined the elements and the combination would have yielded predictable results. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. - , 82 USPQ2d 1385 (2007).

Therefore, the rejection of 11/26/08 is maintained.

6. Applicants' arguments, see Page 8, filed 05/26/09, with respect to the rejection of claim 13 under 35 USC § 103(a) as being unpatentable over Fildes et al. (US

4,202,880) in view of Wunder et al. (US 3,639,157) and further in view of Graham et al. (WO 94/22934) have been fully considered but are not persuasive.

Applicants argue that Graham discloses polyurethaneurea polymers that are quite different from those polyurethanes discussed in Fildes and Wunder. Applicants argue that it is also significant that Graham seeks to improve over the linear block amphipathic polymers of Fildes. Applicants argue that Graham teaches that Fildes polymers are inferior because not all of them are completely insoluble in water and that this is a clear teaching away.

This is not persuasive because Graham is used as a supporting reference that teaches the use of organic solvents such as dichloromethane for testing the solubility of polyurethanes. The primary reference, Fildes, teaches that the linear polymer is soluble in common organic solvents (Col. 1, lines 40-45). One of ordinary skill in the art would know that dichloromethane is a commonly used organic solvent. This is evidenced by the teaching of Graham. One of ordinary skill in the art would therefore find it obvious to test the solubility of the linear polymer in dichloromethane during the process of routine experimentation.

Therefore, the rejection of 11/26/08 is maintained.

NEW REJECTION NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoy et al. (US 4,426,485).

The claimed invention is a water-swellable linear polymer obtainable by reacting together (a) a polyethylene oxide; (b) a C_5 to C_{20} diol, and (c) a difunctional isocyanate.

Hoy teaches a condensation or addition polymer (polyurethane) for thickening (or swelling) produced from an organic diisocyanate, a polyether diol and a dihydroxy hydrophobic compound (the dihydroxy hydrophobic compound is 1,2-hexadecanediol) (Abstract, Col. 32, claim 1, Col. 34, claims 24-28). Table 6 discloses compositions comprising PEG (mol. Wt. 8000), TDI (toluene diisocyanate), and 1,2-hexadecanediol (diol from Example 9).

Therefore, the limitations of claims 1-3 are anticipated by the teaching of Hoy.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-3, 6, 8-12 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fildes et al. (US 4,202,880) in view of Wunder et al. (US 3,639,157).

Fildes teaches a linear copolymer, "substantially devoid of cross-linking, and consisting of a plurality of hydrophilic and hydrophobic regions, and wherein the hydrophilic regions are composed of one or more polyoxyalkylene(s) containing the repeating unit --$(CH_2)_2O$--, --CH_2 $CH(CH_3)O$--, --$(CH_2)_3O$-- and/or --$(CH_2)_4O$--, and the hydrophobic regions are composed of a polyurethane which is obtainable in known general manner from a diisocyanate and one or more dihydroxy compounds ..." (Col. 1, line 64 to Col. 2, line 8). Polyethylene glycol (molecular weight ca. 4000) is used as the polyoxyalkylene component (Col. 4, lines 30-31). 4, 4'-Diphenylmethane diisocyanate is mixed with diethylene glycol, 1,2-propylene glycol and 1,3-butylene glycol (Col. 4, lines 35-38).

Fildes does not expressly teach a diol or decane-1,10-diol (elected species).

Wunder teaches coating textiles with polyurethanes (Col. 1, lines 48-52). Polyethylene glycol, 1,10-decane diol and 4,4'-dicyclohexyl methane diisocyanate are disclosed along with combination of the isocyanate with the polyol (Col. 2, lines 1-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a linear copolymer with polyethylene glycol, a diisocyanate and polyols, as suggested by Fildes, combine it with the polyurethane of polyethylene glycol, 1,10-decane diol and 4,4'-dicyclohexyl methane diisocyanate, as suggested by Wunder, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Wunder teaches that the polyurethane includes suitable polyols such as polyethylene

glycol, suitable polyhydric alcohols such as 1,10-decane diol and suitable isocyanates such as 4,4'-dicyclohexyl methane diisocyanate (Col. 2, lines 1-40).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 1, the limitation of a linear polymer is taught by the linear polymer taught by Fildes (Col. 1, line 64 to Col. 2, line 8). The limitation of reacting together (a) a polyethylene oxide; (b) a difunctional compound, and (c) a difunctional isocyanate is taught by the linear copolymer comprising a mixture of polyethylene glycol, 4, 4'-Diphenylmethane diisocyanate and diethylene glycol, 1,2-propylene glycol and 1,3-butylene glycol, as taught by Fildes (Col. 4, lines 26-38).

Regarding instant claims 2-3, the limitation of the polyethylene oxide with a number average molecular weight of 4000 to 35,000 is taught by the polyoxyethylene of molecular weight 400 to 20,000 (Col. 2, lines 40-42).

Regarding instant claim 6, the limitation of the diol would have been obvious over the 1,10-decane diol taught by Wunder (Col. 2, lines 7-12).

Regarding instant claims 8-12 and 21-22, the limitations of the ratio of components (a) to (b) to (c) and the limitations of the polymer's water swellability would have been obvious over the mixture of polyethylene glycol, 4, 4'-Diphenylmethane

diisocyanate and diethylene glycol, 1,2-propylene glycol and 1,3-butylene glycol, as taught by Fildes (Col. 4, lines 26-38) in view of the polyethylene glycol, 1,10-decane diol and 4,4'-dicyclohexyl methane diisocyanate taught by Wunder (Col. 2, lines 1-40). Fildes teaches that "the degree of hydrophilicity, and therefore of water-swellability, of the copolymer can be pre-determined by its composition" (Col. 1, lines 50-52). Therefore, one of ordinary skill in the art would vary the ratio of these components during the process of routine experimentation in order to achieve the desired degree of hydrophilicity or water swellability. The recited ratio of components (a) to (b) to (c) and the recited percentages of the polymer's water swellability would have been obvious variants unless there is evidence of criticality or unexpected results.

11. Claim 13 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Fildes et al. (US 4,202,880) in view of Wunder et al. (US 3,639,157) and further in view of Graham et al. (WO 94/22934).

Fildes and Wunder do not specifically teach the solubility of the polymer in dichloromethane.

Graham teaches that the polyurethaneurea hydrogels are soluble in certain organic solvents including dichloromethane (Page 17, lines 10-12).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a linear copolymer with polyethylene glycol, a diisocyanate and polyols, as suggested by Fildes, combine it with the polyurethane of polyethylene glycol, 1,10-decane diol and 4,4'-dicyclohexyl methane diisocyanate, as suggested by

Wunder, test the solubility of the polymer in organic solvents such as dichloromethane, as evidenced by Graham, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Fildes teaches that the polymer is soluble in common organic solvents (Col. 1, lines 40-45). One of ordinary skill in the art would know that dichloromethane is a commonly used organic solvent, as evidenced by the teaching of Graham. One of ordinary skill in the art would therefore find it obvious to test the solubility of the linear polymer in dichloromethane during the process of routine experimentation.

Conclusion

12. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615